

## L4

**MEASURING THE IMPACT OF HIPAA'S PRIVACY RULE IN THE PROSTATE, LUNG, COLORECTAL AND OVARIAN (PLCO) CANCER SCREENING TRIAL.** P M Marcus, M Miedzinski (Division of Cancer Prevention, National Cancer Institute, Bethesda MD)

**Introduction:** HIPAA's Privacy Rule became legally mandated on April 14, 2003. Since then, researchers have reported difficulties in obtaining medical records. In PLCO, a randomized controlled trial of screening modalities, patient records are requested from medical facilities and used to complete a Diagnostic Evaluation Form (DE) for each screen that is suspicious for one of the four study cancers. The authors explored time from screen to DE completion before and after 4/13/03 to gauge a possible impact of HIPAA. **Methods:** Positive screens occurring between 4/14/01 and 4/13/03 with DEs completed on or before 4/13/04 and in less than a year (to reflect limited time after 4/13/03) were included. DEs completed prior to 4/14/03 were considered pre-HIPAA (n=2476); those completed on or after 4/14/03 were considered post-HIPAA (n=581). The authors computed the average time to completion in each group, and used T-tests to compare those figures. **Results:** The mean time to completion for pre-HIPAA DEs was 6.25 months (SD: 2.93); for post-HIPAA DEs, it was 8.24 months (SD: 2.81). The difference was statistically significant ( $p < 0.001$ ). **Conclusions:** PLCO DE completion took longer after 4/13/03. Although a delay due to other reasons cannot be ruled out, HIPAA could be responsible. Irrespective of cause, the delay appears not to have negatively affected trial validity, however.

## L6

**INFLUENCES OF PAST AND CURRENT VITAMIN E INTAKE ON SERUM  $\alpha$ -TOCOPHEROL AND ITS ASSOCIATION WITH COGNITIVE IMPAIRMENT IN OLDER WOMEN: A WHI ANCILLARY STUDY.** J E Dunn\*, A Stoddard, S Zilber, S Banks, S Weintraub (New England Research Institutes, Watertown MA 02472; Northwestern University, Chicago IL 60211)

While studies of vitamin E (VITE) intake and cognitive function have been inconsistent; those examining serum or plasma status have been less so. These data from a Women's Health Initiative (WHI) ancillary study (N=526) examine: 1) associations of serum  $\alpha$ -tocopherol levels (Ser-atoc) with cognitive impairment in women age 60+, and 2) influences of previous and current VITE intake on Ser-atoc. **Methods:** Dietary (D) and supplemental (Su) VITE intake were ascertained at WHI baseline. Cognitive testing, Ser-atoc measurement, and supplement data were obtained at ancillary study enrollment, mean 5.6 (SD 2.2) years later. Scores of 2+SD below age- and education-specific norms on 1+tests in a given domain (memory, attention, language, executive and visual functions, or mixed domains) indicated impairment. **Results:** Adjusting for age, education, race, and apoE genotype, lowest quartile of Ser-atoc was associated with memory impairment (Odds Ratio (OR) 1.8; 95% CI 1.1–2.9) and mixed impairment (1.9; 1.01–3.6), while current Su-VITE was not. Previous Su-VITE intake was modestly associated with reduced risk of memory impairment (OR 0.9 per 100mg/day; 95% CI 0.83–0.998); previous D-VITE was not. Adjusting for age, education, race, and time between visits, both previous and current Su-VITE were associated with Ser-atoc ( $p < 0.001$ ); previous D-atoc was not. **Conclusion:** Ser-atoc is associated with memory impairment. However, both previous and current Su-VITE intake are associated with

## L5

**SERUM VITAMIN E AND ALL-CAUSE, CANCER, AND CARDIOVASCULAR DISEASE MORTALITY IN A COHORT OF MALE SMOKERS.** M E Wright\*, S J Weinstein, P Pietinen, P R Taylor, J Virtamo, D Albanes (Division of Cancer Epidemiology and Genetics, National Cancer Institute, NIH, DHHS, Rockville, MD)

Higher blood levels of vitamin E have been associated with reduced risks of major chronic diseases in observational studies. Associations with mortality have been less well studied, however, and results to date have been inconclusive. The authors prospectively examined total and cause-specific mortality in relation to serum  $\alpha$ -tocopherol levels in the Alpha-Tocopherol, Beta-Carotene Cancer Prevention (ATBC) Study. Baseline fasting serum  $\alpha$ -tocopherol concentrations (measured via high-performance liquid chromatography), height, weight, and smoking and medical histories were available for 29,102 male smokers ages 50–69 years old. A total of 13,386 deaths (including 4,522 cancer deaths and 5,778 cardiovascular disease (CVD) deaths) were identified during up to 19 years of follow-up (median=15.7 years). In multivariate proportional hazards models, men in higher quintiles of serum  $\alpha$ -tocopherol had lower risks of all-cause (highest versus lowest quintile, relative risk (RR) = 0.82, 95% confidence interval (CI) = 0.77–0.88,  $p < 0.0001$ ), cancer (RR = 0.80, 95% CI = 0.71–0.90,  $p = 0.0005$ ), and CVD mortality (RR = 0.89, 95% CI = 0.80–0.98,  $p = 0.12$ ) compared to those in the lowest serum quintile. These results suggest that higher circulating concentrations of  $\alpha$ -tocopherol are associated with lower overall, cancer, and, to a lesser extent, CVD mortality in older male smokers.

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## L7

**A POPULATION-BASED COMPARISON OF NONSTEROIDAL ANTI-INFLAMMATORY DRUGS AND THEIR ASSOCIATION WITH ACUTE RENAL FAILURE.** V Schneider\*, L Lévesque, B Zhang, J Brophy (Division of Clinical Epidemiology, Royal Victoria Hospital, 687 Pine Avenue West, Montreal, Quebec, Canada)

**Background:** In contrast to cardiovascular safety, the renal safety profile of selective inhibitors of cyclooxygenase2 (COX2-inhibitors) has not previously been compared to conventional nonsteroidal anti-inflammatory drugs (NSAIDs). **Methods:** A nested case-control study from a cohort of 121,722 new NSAIDs users above 66 years of age was performed using the health insurance databases of Quebec from 01/01/1999 to 31/12/2002. The outcome was hospitalization with a diagnosis of acute renal failure (ARF). Up to 20 controls were selected for each case matched on age and date of cohort entry. Conditional logistic regression was applied, adjusting for sex, age, health status, health care utilization measures, exposure to contrast agents and other nephrotoxic medications. **Results:** During 288,364 person-years of follow-up, 4,228 cases of ARF and 84,540 controls were identified. In current users, compared those unexposed to NSAIDs in the year before the index date, the odds ratio (95% confidence interval) of ARF was 1.3 (1.0–1.7) for conventional NSAIDs, 1.6 (1.4–1.8) for rofecoxib and 1.0 (0.9–1.1) for celecoxib. **Conclusion:** The renal toxicity of the COX2-inhibitor rofecoxib is comparable to conventional NSAIDs, but celecoxib has a lower relative risk for ARF than conventional NSAIDs.

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